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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/285,429 | 04/02/1999 | BRET A. SHIRLEY | 5784-9 | 3707 |

27476 7590 10/14/2003

Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/285,429

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,13,14,21-34,38-40 and 45-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 21-34,45 and 46 is/are allowed.
- 6) ☒ Claim(s) 1-10,13,14,38-40 and 47-52 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 29.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-10, 13, 14, 21-34, 38-40 and 45-52 are pending.

Applicants' amendment filed August 8, 2003 (Paper No. 28) is acknowledged, and applicant's response has been fully considered. Claim 1 has been amended, claims 11, 12, 35-37 and 41-44 have been cancelled, and new claims 45-52 have been added. Therefore, claims 1-10, 13, 14, 21-34, 38-40 and 45-52 are examined.

Objection Withdrawn

2. The previous objection of claims 11, 12 and 41-44 is withdrawn in view of applicants' cancellation of the claim in Paper No. 28.

Rejection Withdrawn

Claim Rejections-Obviousness Type Double Patenting

3. The previous rejection of claims 35-37 under the judicially created doctrine of obviousness-type double patenting, is withdrawn in view of applicants' cancellation of the claim in Paper No. 28.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1-10, 13, 14 and 35-40 under 35 USC § 102(b), as being anticipated by Profitt *et al.* (EP 0317120, May 1989), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 9-10 in Paper No. 28.
5. The previous rejection of claims 35-37 under 35 USC § 102(e), as being anticipated by Cleland *et al.* (US 2002/0004481 A1, filed June 11, 1998), is withdrawn in view of applicants' cancellation of the claim in Paper No. 28.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-8, 13, 14, 38-40 and 47-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 9, 12, 13, 36-40, 45, 47, 48 of copending application US 2002/0172661 A1 (10/035,397).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-8, 13, 14, 38-40 and 47-50 in the instant application disclose a pharmaceutical composition comprising a pharmaceutically active agent and a succinate buffer at a concentration of 7-45 mM. This is obvious in view of claims 1, 6, 9, 12, 13, 36-40, 45, 47, 48 of copending application which disclose a pharmaceutical composition comprising a monomeric interferon-beta solubilized in a low ionic strength formulation, wherein the formulation comprises a buffer (e.g., succinate at about 5 mM) to maintain a pH about 3.0 to about 5.0 and has an ionic strength not greater than about 60 mM. Since the claims of the instant application and those of the copending application are directed to a pharmaceutical composition comprising a pharmaceutically active agent and a succinate buffer, wherein the ionic strength of the composition is not greater than about 60 mM. Thus, claims 1-8, 13, 14, 38-40 and 47-50 in

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present application and claims 1, 6, 9, 12, 13, 36-40, 45, 47, 48 of copending application are obvious variations of a pharmaceutical composition comprising a pharmaceutically active agent and a succinate buffer at a concentration of 7-45 mM.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In response, applicants indicate they will not take any action regarding the provisional rejection since both the instant application and the copending Application No. 10/035,397 are pending, and it is not evident which one will become allowable first. Should the copending application be the first to be in condition for allowance, applicants will, upon notification to this effect, either argue the double-patenting rejection or timely file a terminal disclaimer in the present application (pages 8-9 of the response). The ground of rejection remains in view of applicants' response. No allowable material can be indicated when a ground of rejection remains.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-10, 13, 14 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10, 13, 14 and 38-40 are indefinite because of the use of the term "CNTF", "BNDF" or "TPA". The term "CNTF", "BNDF" or "TPA" renders the claim indefinite, it is not clear what the term means. A fully spelled out word should be indicated in the first occurrence.

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Claims 2-10, 13, 14 and 38-40 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-5, 9, 10, 13, 14, 38-40, 47-49, 51 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Van't Veer *et al.* (U. S. Patent 5,977,057, May 8, 1996).

Van't Veer *et al.* teach a liquid formulation containing tissue factor pathway inhibitor (TFPI, a known peptide inhibitor) in 150 mM NaCl and 20 mM phosphate buffer at pH 7.2, however, TFPI can also be formulated in succinate buffer at the concentration of 0.01 to 0.3 M (corresponding 10-300 mM) as a sterile injectable preparation (column 5, lines 19-55; column 6, lines 26-29; claims 1-5, 9, 10, 13, 38-40, 47-49, 51 and 52). The liquid TFPI formulation can be lyophilized to prevent degradation (column 6, lines 44-46; claim 14).

9. Claims 1-5, 9, 10, 13 and 38-40 are rejected under 35 U.S.C. 102(e) as anticipated by Cleland *et al.* (US 2002/0004481 A1, filed June 11, 1998).

Cleland *et al.* teach an injectable nerve growth factor (NGF) microencapsulate composition, where the suspension of microspheres is prepared with a sterile solution, and the formulation may contain buffer such as succinate in the range of about 2 mM to about 100 mM

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(claims 1-5, 13 and 38-40) and pharmaceutically acceptable salt such as sodium chloride (paragraphs 0136 and 0137; claims 9 and 10).

In response, applicants indicate that Cleland *et al.* teach a controlled-release microencapsulated NGF formulation optionally comprising a buffering agent of succinate at concentration of 2-100 mM, while the claims of the instant application are directed to a sterile injectable pharmaceutical composition comprising a pharmaceutically active agent and a buffer of succinate at a concentration of 7-45 mM and the active agent does not include NGF (page 10 of the response). The response has been fully considered, however, the argument is not found persuasive because NGF is a peptide, which is encompassed in the claim as an active agent. Therefore, the reference anticipates the claimed composition.

Conclusion

10. Claims 1-10, 13, 14, 38-40 and 47-52 are rejected. It appears claims 21-34, 45 and 46 are free of prior art, thus are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Christopher S. Low

October 7, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800